

## REMARKS

Reconsideration of the application is respectfully requested.

The Office has rejected pending claims 1, 3-10, 12-13 and 15-17 under 35 U.S.C. 103(a) as being unpatentable over Reimer et al. (WO 01/37850) in view of O'Callaghan et al. (WO 93/04593). According to the Office it would have been obvious to use the hypoallergenic whey protein hydrolysates taught by O'Callaghan in place of the sweet or acid whey protein in the method of treating diabetes as taught by Reimer.

The Final Rejection provides an extensive rationale for the rejection of the pending claims. The Office, however, has hardly substantiated why it would have been obvious to employ a whey protein hydrolysate which "has a molecular weight profile as measured by SEC-HPLC of 30-40 wt% greater than 10,000 Dalton, 7-12 wt% in the range of 5,000-10,000 Dalton, 15-25 wt% in the range of 2,000-5,000 Dalton and 30-45 wt% less than 2,000 Dalton."

At the bottom of page 9, the Office states: "In regards to Applicant's argument that Tables 2, 4, 6 8 and 10 (of O'Callaghan reference) contain only a minor fraction of material having a molecular weight in excess of 5,000 Daltons, O'Callaghan teaches different ranges of whey protein hydrolysate profile. Therefore, it would have been obvious to one of ordinary skill in the art to optimize the concentrations of the whey protein profile to optimize the GLP-1 secretion and control glucose homeostasis in the subject. Controlling glucose homeostasis (blood/sugar regulation) will regulate the availability of glucose to maximize its energy (ATP) making potential in the body. Therefore, the whey protein hydrolysates taught by Reimer et al. and O'Callaghan et al.

must have all of the characteristics and functionality as the claimed whey protein hydrolysate."

The molecular weight distribution of hypoallergenic whey protein hydrolysates according to O'Callaghan are described in Tables 2, 4, 6, 8 and 10. In addition, O'Callaghan et al. teach that it is desirable to have a certain proportion (approximately 8-15%) of the total polypeptide mixture in the region of 50,000 – 5,000 Daltons to provide emulsion stability in the final infant formula (page 7, lines 24-27).

In the following table, the MW distributions of the whey hydrolysates described by O'Callaghan are compared to the MW-distribution recited by the present claims.

MW (Daltons)	Appln.	O'Callaghan				
		Table 2	Table 4	Table 6	Table 8	Table 10
>10,000	30-45%	<11.2%	<2.3%	<4.9%	<4.8%	<5.03%
10,000- 5,000	7-12%	<11.2%	<2.3%	<4.9%	<4.8%	<4.99%
5,000- 2,000	15-25%	<33.3%	<21.8%	<24%	<23.8%	<26.16%
<2,000	30-45%	>55.4%	>75.9%	>70.5%	>71.4%	>68.82%

The table clearly shows the difference between O'Callaghan's table and present claim 1 at >10,000 Dalton's and <2,000 Daltons.

Thus, even if, as argued by the Office, it would have been obvious to a person of ordinary skill in the art to employ a hypoallergenic whey protein hydrolysate taught by O'Callaghan in the method as taught by Reimer, this would not have led such person to the subject matter of the present claims. Substitution of the whey protein hydrolysates taught by O'Callaghan et al. for that of Reimer et al. would result in the use of a whey

protein hydrolysate that does not exhibit the MW distribution profile that is recited by the present claims.

According to the Office it would have been obvious to one of ordinary skill in the art to optimize the concentrations of the whey protein profile to optimize the GLP-1 secretion and control glucose homeostasis in the subject and the Office seems to imply that such optimization would inevitably lead to a whey protein hydrolysate having the MW-distribution recited by the present claims. However, this reasoning presupposes that a person of ordinary skill in the art would have been motivated to optimize GLP-1 secretion by modifying the MW-distribution of the hydrolysates taught by O'Callaghan. Reimer et al. teaches milk protein hydrolysates that are capable of inducing release of GLP-1. However, the Office points to no teaching by Reimer et al. that GLP-1 secretion can be optimized by varying the MW-distribution of the hydrolysate. Consequently, it would appear that the recited argumentation that it would have been obvious to maximize GLP-1 secretion by optimizing the concentrations of the whey protein MW-profile, enjoys the benefit of proscribed hindsight. Furthermore, even if it would have been obvious to optimize the concentrations of the whey protein MW-profile to maximize GLP-1 secretion, it cannot be seen how this would have led a skilled person to the specific MW-distribution recited by the present claims.

Consequently, it is submitted that the subject matter of the present claims in unobvious merit vis-à-vis Reimer et al. and O'Callaghan et al.

In view of the foregoing, it is respectfully requested that the application be allowed.

Respectfully submitted,



Gerrard J. McGowan, Jr.  
Registration No. 29,412  
Attorney for Applicant(s)

GJM/mpk  
(201) 894-2297